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No. 06-1016

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

RANBAXY LABORATORIES LIMITED and
RANBAXY PHARMACEUTICALS INC.,

Petitioners,

v.

PFIZER INC, PFIZER IRELAND PHARMACEUTICALS
and WARNER-LAMBERT COMPANY, LLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit erred in affirming, under the clear error standard of review, the district court's factual finding that there was no materiality and hence no inequitable conduct in the prosecution of a patent term extension for United States Patent No. 4,681,893.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc states that it has no parent company and no publicly held company owns 10% or more of the stock of Respondent Pfizer Inc. Respondents Pfizer Ireland Pharmaceuticals and Warner-Lambert Company LLC are wholly owned subsidiaries of Pfizer Inc. Warner-Lambert Company and Warner-Lambert Export, Ltd., are the former names of Warner-Lambert Company LLC and Pfizer Ireland Pharmaceuticals, respectively. Respondents are referred to collectively as "Pfizer" in this opposition.

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Pursuant to United States Supreme Court Rule 15, Pfizer hereby submits this brief in opposition to the petition for a writ of certiorari.

STATEMENT OF THE CASE

A. Background

This is a patent case brought by Pfizer against petitioners Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc. (collectively, "Ranbaxy") for infringement of two patents protecting the cholesterol-reducing drug Lipitor®, the world's most widely prescribed drug. Lipitor® has revolutionized the treatment of high cholesterol, a condition that affects millions of people and carries risks of serious cardiovascular events such as heart attacks and strokes. Lipitor® has prolonged countless lives by significantly reducing low-density lipoprotein ("LDL") cholesterol using lower dosages than required with previous "statin" drug treatments.

Both patents in suit, United States Patent No. 4,681,893 (the "'893 patent") and United States Patent No. 5,273,995 (the "'995 patent"), claim atorvastatin calcium, the active ingredient in Lipitor®. The earlier-filed '893 patent claims a class of compounds embracing atorvastatin calcium. After years of additional work following this genus invention, the same inventor further improved the invention by discovering that, within the broader class of compounds claimed by the '893 patent, atorvastatin calcium in particular possessed unique properties for reducing cholesterol. The '995 patent was filed to further protect this compound.

After the '893 patent issued, Pfizer filed an application for a term extension of some of the '893 patent claims

pursuant to 35 U.S.C. § 156, which authorizes such an extension based on regulatory delay stemming from the "regulatory review period [for a drug] before its commercial marketing or use." Pfizer based its application upon the regulatory delay attendant to obtaining approval to market Lipitor®. The application identified Lipitor®'s active agent as atorvastatin calcium, and demonstrated why this compound fell within each of the claims on which it based the extension. The United States Patent and Trademark Office (the "PTO") agreed with Pfizer, granted the application and extended the term of the '893 patent claims until September 24, 2009. Pet. App. 20-21. The United States Food and Drug Administration ("FDA") granted an additional period of marketing exclusivity pursuant to the pediatric exclusivity provisions of the Food, Drug and Cosmetic Act. 21 U.S.C. § 355a.

B. The Litigation Below

After Ranbaxy filed Abbreviated New Drug Application No. 76-477 with the FDA, seeking to sell a generic drug containing atorvastatin calcium as its active ingredient, Pfizer brought the present action, alleging that Ranbaxy's proposed generic drug infringed claims 1-4, 8 and 9 of the '893 patent and claim 6 of the '995 patent. Ranbaxy argued that its product did not infringe either patent, that the term extension for the '893 patent was invalid, and that the '995 patent was invalid on several grounds. Following a bench trial in November and December 2004, the district court ruled in favor of Pfizer on all of the foregoing issues. Appendix to Petition for Writ of Certiorari filed January 22, 2007, at pages 71-72.[1]

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[1] Hereinafter cited as "Pet. App. __."

The district court held, contrary to Ranbaxy's claim construction arguments, that the '893 patent covered atorvastatin calcium because it was not limited to a class of chemical compounds called "racemates," *i.e.*, compounds containing equal mixtures of two molecules (each called "enantiomers") sharing the same number, type, and arrangements of atoms. The district court found that the '893 patent "is not limited to racemates," and thus its claims embraced the compound atorvastatin calcium, which is an enantiomer within the scope of the '893 patent claims. Pet. App. 24-32.

In reaching its construction of the '893 claims, the district court rejected Ranbaxy's attempt to use certain statements made during the prosecution of the '995 patent to limit the scope of the '893 patent. The district court first noted that decisions of the Federal Circuit had limited the circumstances under which statements made during a subsequent patent prosecution could be used to construe an earlier-issued patent. Pet. App. 31. The district court cited *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated on other grounds*, 545 U.S. 193 (2005), and several other Federal Circuit decisions to support this proposition. Pet. App. 31, 31 n. 3.

Nevertheless, the district court went on to examine the statements on their merits, and to expressly hold, in the alternative, that the statements made in connection with the later '995 patent prosecution were not "irreconcilably inconsistent" with the conclusion that the '893 patent claimed enantiomers. Pet. App. 31-32. In the statements relied upon by Ranbaxy, Pfizer had merely noted that the enantiomers claimed in the '995 patent were not expressly named, exemplified or depicted in the '893 patent, thus precluding

anticipation of the '995 claims. These statements, relating solely to *anticipation,* the only question then at issue, were entirely consistent with the fact that the '893 claims embraced those enantiomers. The same is true regarding the mere existence of the '995 patent. Ranbaxy's allegations of inconsistency ignore two overarching principles of patent law. First, a patent, like '893, claiming a genus of chemical compounds, embraces all species within that genus, even if they are not expressly named in the disclosure. *Eli Lilly & Co. v. Board of Regents of Univ. of Washington*, 334 F.3d 1264, 1268 (Fed. Cir. 2003), *cert. denied*, 541 U.S. 896 (2004). Second, a later patent, like '995, may validly claim any non-disclosed species of an earlier genus patent that, though included within the genus, a skilled artisan would not previously have been motivated to develop. *Id.* at 1270. Based on these well-known principles, atorvastatin calcium is an unnamed species within the genus of compounds claimed in the '893 patent but it is also independently patentable in the '995 patent as a selection invention. *See, e.g., In re May*, 574 F.2d 1082, 1090 (C.C.P.A. 1978) (holding that "the novelty of an optical isomer is not negated by the prior art disclosure of its racemate"); *Eli Lilly & Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096, 1104 (5th Cir. 1972); *In re Williams*, 171 F.2d 319, 320 (C.C.P.A. 1948). Thus, the district court concluded that "[t]he arguments Pfizer made in the '995 prosecution were directed to the issue whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis." Pet. App. 32.

The district court also rejected Ranbaxy's challenge to the validity of the term extension of the '893 patent. Ranbaxy challenged the extension on two grounds. First, Ranbaxy argued that the extension was categorically unavailable

because it was premised upon the regulatory delay attendant to approval of the drug Lipitor®, but the '893 patent did not cover Lipitor® (because, Ranbaxy contended, it was limited to racemates). The district court noted that this argument was entirely derivative of Ranbaxy's claim construction argument, which the district court had already rejected. Pet. App. 41-42. The district court noted that "[t]he PTO agreed with Pfizer's construction and concluded that the active ingredient in Lipitor® fell within the scope of the '893 patent." Pet. App. 42.

Ranbaxy also challenged the patent term extension, alleging that Pfizer had engaged in inequitable conduct by failing to disclose to the examiner the statements made in the course of the '995 patent prosecution regarding anticipation. Pet. App. 41. The district court noted that, under 37 C.F.R. § 1.765(a), there is "a duty to disclose 'material information adverse to a determination of entitlement to the extension sought,' "and that "[i]nformation is considered material 'where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." Pet. App. 41 (second set of brackets and ellipsis in district court decision). Applying this well-established standard, the district court observed that:

> [i]n the context of its claim construction, [it] ha[d] concluded that the disclosures . . . in connection with the prosecution of the '995 patent . . . [we]re irrelevant to a determination of the scope of the claims of the '893 patent. Because this information [wa]s not relevant to the patent's scope, the Court conclude[d] that Ranbaxy ha[d] not established that the allegedly withheld

> information [wa]s material such that it was required to be disclosed during the application process for the patent term extension.

Pet. App. 43.

Having concluded that the statements were not material to the patent term extension, the district court did not need to reach the *intent to deceive* prong of the inequitable conduct analysis.

Turning to the '995 patent, the district court rejected Ranbaxy's claim construction argument and held that claim 6 of the '995 patent also claimed atorvastatin calcium. The district court also rejected Ranbaxy's invalidity and unenforceability arguments with respect to that patent. Pet. App. 32-40, 43-70.

On appeal, the Federal Circuit affirmed in part and reversed in part. The panel affirmed the district court's claim construction of the '893 patent, concluding that the district court had correctly construed the '893 patent to embrace Lipitor®. Pet. App. 11. The panel agreed with the district court that Ranbaxy could not rely on the statements regarding anticipation made during the '995 prosecution. The panel cited *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158 (Fed. Cir. 2004), and other cases, for the proposition that such extrinsic statements could not alter the meaning of a previously issued patent, and rejected Ranbaxy's argument both as a matter of claim construction and "under the guise of judicial estoppel . . .". Pet. App. 11.

The panel also affirmed the district court's holding that the term extension for the '893 patent was valid. Like the

district court, the panel expressly noted that "the patentee has a duty of candor and good faith towards the PTO and must disclose any 'material information adverse to a determination of entitlement to the extension sought.'" Pet. App. 12 (quoting 37 C.F.R. § 1.765(a)). The panel found the term extension was properly granted because the '893 patent did cover atorvastatin calcium; the panel found that Ranbaxy's argument to the contrary "depend[ed] on [Ranbaxy's] claim construction, which we have already rejected." Pet. App. 12.

The panel also affirmed the district court's rejection of Ranbaxy's inequitable conduct attack on the term extension. The panel noted that "the district court found that the allegedly withheld information was not material, and consequently did not need to be disclosed to the PTO . . .". Pet. App. 12. It adopted this factual determination without substantial discussion: "This factual finding was not clearly erroneous. We thus agree that Ranbaxy failed to establish by clear and convincing evidence that the term extension was invalid." Pet. App. 12.

The panel held that claim 6 of the '995 patent was invalid for failure to comply with the technical requirements of the fourth paragraph of 35 U.S.C. § 112, which prescribes the format for dependent claims. Pet. App. 12-16.

Ranbaxy petitioned the panel for rehearing, and the full Federal Circuit for rehearing *en banc*. Ranbaxy's rehearing petition included arguments, similar to those presented here, that the '893 patent term extension was invalid. On October 23, 2006, the Federal Circuit denied these petitions without dissent from any Judge of that court, Pet. App. 80-81, presumably after finding Ranbaxy's Petition for Rehearing

En Banc presented no question of exceptional importance nor any evidence of conflicting decisions appropriate for *en banc* consideration. *See* Fed. R. App. P. 35(a); Fed. Cir. R. 35(b).

REASONS FOR DENYING THE PETITION

Ranbaxy petitions for review of a question regarding the application of "the statute and regulation mandating disclosure of all material information to the Patent Office by a pharmaceutical company seeking a patent term extension . . .". Petition for Writ of Certiorari filed January 22, 2007, at page i.[2] However, the Federal Circuit decided no such issue in this case. The Federal Circuit's patent term extension ruling was a clear error affirmance of a district court factual finding rejecting allegations of inequitable conduct in the prosecution of a patent term extension. No member of the panel dissented from this factual ruling or voted for rehearing, and no Judge of the Federal Circuit dissented from the decision not to hear the issue *en banc*.

Implicitly recognizing that this Court does not review such routine factual determinations, Ranbaxy attempts to transform it into a legal ruling purportedly abrogating the federal regulations relating to disclosures of material information. At its essence, however, this argument boils down to the proposition that, because the Federal Circuit was allegedly wrong in affirming the finding that the statements underlying the inequitable conduct charge were immaterial, this constituted a legal ruling refusing to defer to those regulations. The decision below made no such ruling, which is why the Petition cannot cite any language from the decision

[2] Hereinafter cited as "Pet. __".

under review announcing the alleged "*per se* rule" it petitions this Court to review.

I. THE PETITION RAISES NO IMPORTANT OR RECURRING ISSUE WARRANTING THIS COURT'S REVIEW

A. The Federal Circuit's Clear Error Affirmance Rested On A Purely Fact-Bound, Case-Specific Determination Regarding the Materiality of the Particular Statements in This Case.

The petition raises no important or recurring issue that warrants this Court's review. This Court will expend its limited resources to review a case only where there are "compelling reasons" for doing so, including "important question[s] of federal law." Supreme Court Rule 10, 10(c). A fact-bound issue involving no generally applicable issue of law does not rise to that standard, and hence does not warrant review by this Court. *See, e.g., Rudolph v. United States*, 370 U.S. 269, 269-70 (1962) (per curiam) (dismissing writ of *certiorari* because legal issues were not presented in the case and noting that questions regarding "ultimate facts" that "are subject to the 'clearly erroneous' rule" do not warrant review by this Court); *United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts."). This rule applies with even greater force where the court of appeals and the district court agreed on the factual question. "[A] court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional show of error." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949); *accord, e.g.*,

Branti v. Finkel, 445 U.S. 507, 512 n.6 (1980) (noting "our settled practice of accepting, absent the most exceptional circumstances, factual determinations in which the district court and the court of appeals have concurred").

The ruling below that statements made during the prosecution of the '995 patent were immaterial for purposes of the '893 patent term extension is precisely a fact-based determination that does not warrant review by this Court. Ranbaxy's argument is that certain statements from the '995 patent prosecution should have been considered on their merits, and should not have been held legally irrelevant to a patent term extension. But in fact, the district court *did* review these statements on the merits, and held, on the facts, that they were not "irreconcilably inconsistent" with the construction underlying the term extension. Pet. App. 32. The district court explained that "[t]he arguments Pfizer made in the '995 prosecution were directed to the issue of whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis." Pet. App. 32. The district court's rejection of Ranbaxy's inequitable conduct allegation rested upon that factual decision; the district court found that "the disclosures made ... in connection with the prosecution of the '995 patent ... are irrelevant to a determination of the scope of the claims of the '893 patent." Pet. App. 43.

The Federal Circuit affirmed that finding of fact as "not clearly erroneous." Pet. App. 12. By its terms, this affirmance did not apply any new principle of law, let alone a new "*per se* rule" allowing the non-disclosure of "inconsistent" statements as imagined by the petition. Pet. i. To the contrary, the decision below affirmed an express finding that the statements in question were *not* "inconsistent." Pet. App. 12,

32. Because the decision below rested upon a question of fact reviewed for clear error, *see Rudolph*, 370 U.S. at 269-70, and one regarding which the court of appeals and the district court concurred, *see Graver Tank & Mfg. Co.*, 336 U.S. at 275, it does not raise any issue warranting review by this Court.

B. This Case is Not an Appropriate Vehicle for Reviewing the Circumstances Under Which Statements Made in an Unrelated, Subsequent Patent Prosecution May be Considered in Construing the Claims of an Earlier Patent, and That Issue Would Not Warrant Review in Any Event.

Ranbaxy suggests that this case implicates decisions of the Federal Circuit, such as *Integra* and *Goldenberg*, holding "that a patentee's representations to the Patent Office during prosecution of a later, formally-unrelated patent application cannot be used to construe the claims of an earlier-issued patent to the same patentee." Pet. 23 (footnote omitted). That issue is not presented here, and would not warrant review by this Court even if it were.

First, where a decision under review does not actually present the question in a petition for *certiorari*, the case is an improper vehicle for deciding that issue. *See, e.g., Tacon v. Arizona*, 410 U.S. 351, 351 (1973) (per curiam); *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 140 (1998) (Court will not review matters "outside the questions presented for certiorari."). As Ranbaxy concedes, Pet. 23, the issue in *Integra* and *Goldenberg* was one of claim construction, not patent term extension. The only possible way the issue presented in the Petition could relate to the term extension

of the '893 patent would be if the statements underlying Ranbaxy's inequitable conduct argument indicated that, as a matter of claim construction, the pertinent '893 patent claims did not, in fact, include enantiomers, and, consequently, that the patent was not entitled to a term extension. Yet the petition does not challenge the Federal Circuit's claim construction ruling that the '893 patent does include enantiomers. Nor does the petition challenge the rulings below rejecting Ranbaxy's argument that the '893 patent term extension is invalid because the '893 patent does not cover enantiomers. Having challenged only the Federal Circuit's inequitable conduct ruling, the petition presents no independent basis to review claim construction principles outside the scope of the question presented. *See, e.g., Tacon*, 410 U.S. at 351.

Second, a case presents an inappropriate vehicle to decide an issue where that issue is purely academic in the case at hand, and cannot affect the outcome however it is resolved. *See, e.g., Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955) (noting that issue should be "beyond the academic or the episodic" to warrant review). The claim construction issue of when subsequent statements in unrelated patent prosecutions can be used to construe an earlier-issued patent would be a purely academic question in this case. The issue could not possibly affect the outcome, because the courts below did examine the subsequent statements relied upon by Ranbaxy on their merits, and found that, even if they were properly considered as relevant, they still would not have altered the scope of the '893 patent claims because they addressed different issues from those relevant to the term extension. Consequently, the courts below concluded the statements would not have been material to the term extension of the '893 patent. Pet. App. 32. Because the courts below have already determined that the statements

in question could not affect the outcome even if they were permissibly considered, the issue of whether they should have been considered is a purely academic question that is unsuitable for this Court's review. *See Montana v. Imlay*, 506 U.S. 5, 6 (1992).

Moreover, the courts below did not reach an additional alternative ground for their decisions that would also render the *Integra/Goldenberg* issue superfluous. In light of the holdings below that the statements at issue were immaterial, the courts below did not need to decide whether the applicable *mens rea* requirement could have been satisfied even if the statements had been material. Pfizer demonstrated at trial that Ranbaxy could not make that showing under the clear and convincing standard of proof. This independent ground supporting the inequitable conduct holding further demonstrates that the *Integra/Goldenberg* issue was purely academic, and could not affect the outcome of the case.

Third, the claim construction issue regarding when statements from later patent prosecutions should be considered in construing earlier patent claims would not warrant this Court's review even if it had been squarely presented in this case. Contrary to the petition, Ranbaxy itself conceded below that the Federal Circuit does *not* apply the principle regarding consideration of statements made in subsequent prosecutions as a blanket, *per se* rule in the claim construction context. Rather, the Federal Circuit's analysis involves a case-specific determination of the statements at issue, and the Federal Circuit permits flat inconsistencies (such as were found not to exist in this case) to be considered in appropriate cases. *See* Ranbaxy Opening Fed. Cir. Brief at 29-31 (Jan. 12, 2006); *Goldenberg*, 373 F.3d at 1167 (characterizing the Federal Circuit's allowance of such

statements as "narrow," not wholly unavailable); *Microsoft Corp. v. Multi-Tech Sys.*, Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004), *cert. denied*, 543 U.S. 821 (2004) ("We rejected the argument that the patentee was bound, or estopped, by a statement made in connection with a later application on which the examiner of the first application could not have relied. We did not suggest, however, that such a statement of the patentee as to the scope of the disclosed invention would be irrelevant."). Because the Federal Circuit does not apply any *per se* rule prohibiting any and all consideration of statements from subsequent, unrelated patent prosecutions, the issue presented in the petition is wholly illusory and cannot justify review by this Court.

II. THE FEDERAL CIRCUIT'S DECISION WAS CORRECT

Finally, the decision below was correct on the merits. The petition is wrong in arguing to the contrary.

A. The Meaning Of An Issued Patent Claim Should Not Ordinarily Be Changed After The Fact By Later, Extrinsic Statements In An Unrelated application.

The Federal Circuit's approach disfavoring consideration of statements made in subsequent patent prosecutions, as set out in *Integra*, *Goldenberg*, and related decisions, reflects the unexceptional rule that the meaning of an issued patent claim should not ordinarily be changed after the fact by later, extrinsic statements in an unrelated application. *See, e.g.*, *Snow v. Lake Shore & M S R Co.*, 121 U.S. 617, 624 (1887) ("The question of infringement turns upon the construction to be given to the first claim of the patent sued on, to

determine which it is necessary to consider the state of the art at the time of its date.") As the Federal Circuit noted in *Integra*, a subsequent, unrelated "patent prosecution does not directly limit the [earlier-issued] patent." 331 F.3d at 869. Moreover, any such statements in the subsequent prosecution may "arise in a context different from the patentability of the [first] patent." *Id.* The petition does not even address these valid legal justifications for the Federal Circuit's approach; to the contrary, it wrongly states that "the Federal Circuit has failed to explain" the rationale for these decisions. Pet. 24.

B. The Federal Circuit's Approach To The Use Of Statements From Subsequent Unrelated Patent Prosecutions Is Fully Consistent With The Statute And Regulations Governing Patent Term Extensions.

The Federal Circuit's approach to the use of statements from subsequent, unrelated patent prosecutions is also fully consistent with the statute and regulations governing patent term extensions, contrary to the petition. Pet. 2, 4-6, 15-19. The statute relied upon by Ranbaxy merely authorizes the PTO to prescribe requirements in connection with patent term extensions. *See* 35 U.S.C. § 156(d)(4). And the regulation relied upon by Ranbaxy merely states a general materiality standard for disclosures in the patent term extension context. *See* 37 C.F.R. § 1.765(a) (requiring disclosure "of material information adverse to a determination of entitlement to the extension sought"). The regulations have nothing to do with claim construction, let alone with the question of whether statements made in subsequent patent prosecutions can modify the scope of an earlier-issued patent claim.

Far from "failing to apply" the materiality standard imposed by the governing regulation, both decisions below expressly applied it and found, on the facts, that it had not been violated. Pet. App. 11-12, 41. Indeed, the petition admits as much in passing (although it characterizes this application as "pa[ying] lip-service"). Pet. 17. Therefore, contrary to the petition's claims that the decision below "refused to apply the Patent Office's regulations," Pet. 6, both the district court and the Federal Circuit did explicitly apply them, and the decision below is entirely consistent with those regulations.

C. The Decision Below Is Also Consistent With This Court's Precedents, And Other Decisions Of The Federal Circuit.

The petition claims that the decision below contravened this Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), by failing to give "the Patent Office's regulation controlling weight . . .". Pet. 20. But the administrative deference required by *Chevron* and related cases is entirely irrelevant, because both the district court and the Federal Circuit below expressly accepted and applied the regulations in question. Pet. App. 11-12, 41. Ranbaxy merely disagrees with the courts' application of those regulations. The PTO has never adopted Ranbaxy's position regarding the consideration of statements from subsequent patent prosecutions as a matter of interpreting any statute within its cognizance. Therefore, Ranbaxy's argument is misguided, and the decision below is fully consistent with *Chevron*. *See, e.g., United States v. Haggar Apparel Co.*, 526 U.S. 380, 391 (1999) ("Deference can be given to the regulations without impairing the authority of the court to make factual determinations, and to apply those determinations to the law, *de novo*.").

The petition also claims that the decision below was inconsistent with Federal Circuit precedent regarding the use of extrinsic evidence in claim construction. Pet. 22-23. No Federal Circuit case has ever held that there can be no limits to the permissible consideration of extrinsic evidence; the authority relied upon by Ranbaxy merely establishes that there is no uniform rule *against* the use of extrinsic evidence in all circumstances, and not that there is a rule *requiring* use of particular extrinsic evidence. Pet. App. 22 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317-19 (Fed. Cir. 2005) (*en banc*). The Federal Circuit's cases relating specifically to the circumstances under which statements from subsequent prosecutions may be considered in construing patent claims merely address the contours of permissible extrinsic evidence in one area, and are fully consistent with the Federal Circuit's broader approach to extrinsic evidence.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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